Initial Approval Date: July 10, 2019
Revised Date: January 20, 2021

CRITERIA FOR PRIOR AUTHORIZATION

Asthma Agents

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in Table 1 below.

Benralizumab (Fasenra®)
Dupilumab (Dupixent®)
Mepolizumab (Nucala®)
Omalizumab (Xolair®)
Reslizumab (Cinqair®)

GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, and not exceed dosing limits listed in Table 1.
- Must be prescribed by or in consultation with a pulmonologist, allergist, or immunologist.[1,2]
- For all agents listed, the preferred PDL drug, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.
- Must have experienced ≥ 2 exacerbations within the last 12 months despite meeting all of the following (exacerbation is defined as requiring the use of oral/systemic corticosteroids, urgent care/hospital admission, or intubation:
  - ~~Exacerbation is defined as requiring the use of any of the following:~~
    - ~~Oral/systemic corticosteroids~~
    - ~~Urgent care or hospital admission~~
    - ~~Intubation~~
  - Patient ~~must be taking~~adherence to two long-term controller medications, including a high-dose inhaled corticosteroid (ICS) and a long-acting beta$_2$-agonist (LABA) listed in Table 2.[1,2]
    - Combination ICS/LABA and ICS/LABA/LAMA products meet the requirement of ~~are considered as~~ two controller medications. ~~Patient must be 80% adherent on all long-term controller medications.~~
  - Patient must have had an adequate trial (at least 90 consecutive days) of or contraindication to a leukotriene modifier or a long-acting muscarinic antagonist (LAMA) as a third long-term controller medication listed in Table 2.
- Prescriber has submitted the patient's baseline FEV$_1$ value.
- For benralizumab, mepolizumab, and reslizumab: patient must have a confirmed eosinophilic phenotype, defined by blood eosinophils of greater than or equal to 150 cells/mcL at baseline.[3,4,5,10]
- For omalizumab, the patient must have a positive skin test or in vitro reactivity to a perennial aeroallergen.[7]
- For dupilumab: patient must have one of the following:
  - A confirmed eosinophilic phenotype, defined as blood eosinophils of greater than or equal to 150 cells/mcL at baseline.[6]
  - Corticosteroid dependent asthma, defined as daily oral corticosteroid (at least 5 mg per day of prednisone/prednisolone or equivalent).[6,8,9]
- For all requested biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another biologic or JAK inhibitor listed in Table 3. After discontinuing the current biologic or JAK inhibitor, the soonest that a new biologic or JAK inhibitor will be authorized is at the next scheduled dose.

~~APPROVED~~ DRAFT PA Criteria

Table 1. FDA-approved age and dosing limits for a~~A~~sthma agents

Medication	Indication(s)	Age	Dosing Limits
Interleukin-4 Receptor Antagonists			
Dupilumab (Dupixent®)	Moderate to severe asthma - eosinophilic phenotype Moderate to severe asthma - corticosteroid dependent Moderate to severe asthma with comorbid atopic dermatitis	≥ 12 years	600mg SC initially, then 300mg every other week.
Interleukin-5 Antagonists			
Benralizumab (Fasenra™)	Severe Asthma	≥ 12 years	30 mg SC every 4 weeks for the first 3 doses, and then every 8 weeks.
Mepolizumab (Nucala®)	Severe Asthma	≥ 6~~12~~ years	6 - 11 years: 40 mg SQ every 4 weeks. 12 years and older: 100 mg SC every 4 weeks.
Reslizumab (Cinqair®)	Severe Asthma	≥ 18 years	3 mg/kg IV once every 4 weeks.
IgG monoclonal antibodies (IgE Inhibitors)			
Omalizumab (Xolair®)	Moderate to Severe Asthma	≥ 6 years	375mg SC every 2 weeks (dosing is based on weight and pretreatment IgE level).

SC: subcutaneous. IV: intravenous.

LENGTH OF APPROVAL (INITIAL): 12 months

CRITERIA FOR RENEWAL PRIOR AUTHORIZATION: (must meet all of the following)

- Patient demonstrates at least one of the following:
  - A decrease in frequency of exacerbations from baseline (defined as a reduction of oral/systemic corticosteroids of at least 50% and/or asthma-related hospitalization and/or asthma-related emergency department visits).[2]
  - Improved lung function, defined as an FEV_1 increase of at least 100mL over baseline.
- Must not exceed dosing limits listed in Table 1.
- For all requested biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another biologic or JAK inhibitor listed in Table 3. After discontinuing the current biologic or JAK inhibitor, the soonest that a new biologic or JAK inhibitor will be authorized is at the next scheduled dose.

LENGTH OF APPROVAL (RENEWAL): 12 months

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

Table 2. List of conventional therapy in the treatment of asthma

Inhaled Corticosteroids (ICS)	**Long-Acting Beta-Agonists (LABA)**	**~~ICS/LABA~~ Combination Agents**	**Long-Acting Muscarinic Antagonists (LAMA)**	**Leukotriene Modifiers**
Beclomethasone (Qvar)	Salmeterol (Serevent)	Fluticasone/Salmeterol (Advair, AirDuo, Wixela)	~~Fluticasone/Umeclidinium/Vilanterol (Trelegy Ellipta)~~Tiotropium (Spiriva)	Montelukast (Singulair)
Budesonide (Pulmicort)	Formoterol (Perforomist)	Budesonide/Formoterol (Symbicort)		Zafirlukast (Accolate)
Ciclesonide (Alvesco)		Mometasone/Formoterol (Dulera)		Zileuton (Zyflo)
Flunisolide (Aerospan)		Fluticasone/Vilanterol (Breo Ellipta)		
Fluticasone (Flovent, Armonair, Arnuity)		Fluticasone/Umeclidinium/Vilanterol (Trelegy Ellipta)		
Mometasone (Asmanex)				

Table 3. List of biologic agents/janus kinase inhibitors (agents not to be used concurrently)

Biologic Agents/Janus Kinase Inhibitors		
Abrilada™ (adalimumab-afzb)	Hadlima™ (adalimumab-bwwd)	Rinvoq™ (upadacitinib)
Actemra® (tocilizumab)	Hulio™ (adalimumab-fkjp)	Rituxan® (rituximab)
Amevive® (alefacept)	Humira® (adalimumab)	Ruxience™ (rituximab-pvvr)
Amjevita™ (adalimumab-atto)	Hyrimoz™ (adalimumab-adaz)	Siliq® (brodalumab)
Avsola™ (adalimumab-axxq)	Ilaris® (canakinumab)	Simponi® (golimumab)
Cimzia® (certolizumab)	Ilumya™ (tildrakizumab-asmn)	Simponi Aria® (golimumab)
Cinqair® (reslizumab)	Inflectra® (infliximab-dyyb)	Skyrizi™ (Risankizumab)
Cosentyx® (secukinumab)	Ixifi™ (infliximab-qbtx)	Stelara® (ustekinumab)
Cyltezo™ (adalimumab-adbm)	Kevzara® (sarilumab)	Taltz® (ixekizumab)
Dupixent® (benralizumab)	Kineret® (anakinra)	Tremfya® (guselkumab)
Enbrel® (etanercept)	Nucala® (mepolizumab)	Truxima™ (rituximab-abbs)
Entyvio® (vedolizumab)	Olumiant® (baricitinib)	Tysabri® (natalizumab)
Erelzi™ (etanercept-szzs)	Orencia® (abatacept)	Xeljanz® (tofacitinib)
Eticovo® (etanercept-ykro)	Remicade® (infliximab)	Xeljanz XR® (tofacitinib)
Fasenra® (benralizumab)	Renflexis® (infliximab-abda)	Xolair® (omalizumab)

References

1. National Heart, Lung, and Blood Institute. National Asthma Education and Prevention Program. Expert Panel on the Management of Asthma. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. Full Report 2007. Bethesda, MD: US Department of Health and Human Services, National Institutes of Health, National Heart, Lung, and Blood Institute; 2007. https://www.nhlbi.nih.gov/health-topics/guidelines-for-diagnosis-management-of-asthma. Accessed 12/07/20.
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3. NUCALA (mepolizumab) [package insert]. Philadelphia, PA: GlaxoSmithKline LLC; September 2020.
4. CINQAIR (reslizumab) [package insert]. ~~Frazer~~West Chester, PA: Teva Respiratory, LLC; ~~Jan 2019~~~~February~~June 2020.
5. Fasenra (benralizumab) [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; ~~Nov 2017~~October 2019.
6. Dupixent (dupilumab) [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc., Sanofi-Aventis US, LLC; ~~Mar 2019.~~June 2020.
7. Xolair (omalizumab) [package insert]. South San Francisco, CA: Genentech, Inc.; ~~May 2019~~November 2020.
8. Efficacy and Safety of Dupilumab in Glucocorticoid-Dependent Severe Asthma. N Engl J Med. 2018 Jun 28;378(26):2475-2485. doi: 10.1056/NEJMoa1804093. Epub 2018 May 21.
9. ClinicalTrials.gov [Internet]. Identifier: NCT02528214, Evaluation of Dupilumab in Patients with Severe Steroid Dependent Asthma (VENTURE). https://clinicaltrials.gov/ct2/show/NCT02528214. Accessed July 2019.
10. Holguin F, Cardet JC, Chung KF, et al. Management of severe asthma: a European Respiratory Society/American Thoracic Society guideline. European Res J 2020;55(1):1-21. https://erj.ersjournals.com/content/erj/55/1/1900588.full.pdf. Accessed on 12/07/2020.

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